



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Template Version 2.08

Required Report - Public distribution

**Date:** 8/10/2007

**GAIN Report Number:** RO7004

## Romania

## FAIRS Country Report

## Annual

## 2007

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**Report Highlights:** Sections Updated: Labeling Requirements, Pesticide and Other Contaminants, Other Regulations and Requirements (Veterinary Regulations), Import Procedure.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Annual Report  
Bucharest [RO1]  
[RO]

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**DISCLAIMER:**

*This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Bucharest, Romania for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.*

## SECTION I. FOOD LAWS

Several different Government agencies and ministries in Romania have responsibilities related to agri-food production and food importation. The pace of transposing the EU regulations accelerated during the second half of 2006 before accession, and continued through 2007. Some of the regulations were enforced at the moment of accession, while others were enforced prior to this date.

The most relevant legal provisions governing agricultural production, food processing and agri-food products, applicable to both domestic and imported products, are outlined below:

- Government Ordinance 42/2004 regarding the organization of veterinary activity with subsequent amendments;
- Government Decision 106/2002 concerning food labeling with subsequent amendments;
- Government Ordinance 34/2000 concerning organic food amended by MARD Order 219/2007 providing instructions for producers, processors, and importers of organic products
- Emergency Ordinance 43/2007 transposing [Directive 2001/18](#) regarding the deliberate release into the environment of genetically-modified organisms
- Emergency Ordinance 44/2007 transposing [Directive 90/219](#) referring to contained use of genetically-modified micro-organisms.

The main bodies with responsibilities covering agricultural production, food processing as well as food importation are the following:

### **The Ministry of Agriculture and Rural Development (MARD)**

The Ministry of Agriculture and Rural Development is the specialized body of the central public administration with governmental jurisdiction. It applies the Government's strategy in the field of agriculture, food processing, as well as rural development and forests management.

### **The Ministry of Environment and Sustainable Development (MESD)**

Ministry of Environment and Sustainable Development is the main body conducting environmental risk assessment (including for genetically modified organisms) and monitoring activities that might have adverse effects on human health and the environment.

### **The Veterinary and Food Safety National Authority (VFSNA)**

This is the main body in charge with sanitary-veterinary and food-safety activities. The Authority performs activities related to animal health and foodstuffs of animal and non-animal origin, as well as food safety.

### **The Ministry of Public Health (MPH)**

The Ministry of Public Health is responsible for overseeing the production and registration of drugs, food additives, and medical equipment. It is also responsible for the public health as it relates to food and contaminants.

### **The National Authority for Consumers Protection (NACP)**

The National Authority for Consumers Protection is the Government agency established with the aim of protecting the consumers' rights and interests. NACP is actively involved in proposing, endorsing and promoting legislation related to consumer protection, including food products.

## **SECTION II. LABELING REQUIREMENTS**

### **A. General Requirements**

The methodology and requirements for food labeling are set out in the GOR Decision 106/2002 - further detailed in its accompanying Methodological Norm 7/2002. The Decision has been recently amended again through GOR Decision 1357/2006, without bringing significant changes though (please see the [GAIN Report 6016](#)).

### **B. Biotechnology Labeling**

The national legislation on requirements for labeling foodstuffs that are based on GMO products or contain additives that have been genetically modified was fully brought in line with the current EU requirements ([Regulation \(EC\) No 1830/2003](#)) through GOR Decision No. 173/2006. Romania adopted measures on thresholds for labeling, set at 0.9% for an adventitious presence of an authorized GM in food or feed. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable.

Animal feed, if produced from GM crops, is required to be labeled, according to GOR Decision 256/2006 in place starting with January 1, 2007. Nevertheless, meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

### **C. Organic Labeling**

Imported products should be labeled as "organic" if they were produced by organic methods confirmed by the certificate of compliance. According to GOR Ordinance 34/2000, the product label must contain: the name and the address of the producer/processor, the name of the product and the ecological production method, the name and the mark of the inspecting and certifying institution, the storage conditions, the minimum term of validity, the interdiction to store the ecological products along with ordinary products.

In 2006, Min. of Agriculture and NACA approved Order 317/2006 stating that for organic food labeling and advertisement the emblem "ae" (**a**gricultura **e**cologica = organic agriculture) should be used. The emblem belongs to the Ministry of Agriculture and can be applied on the product, on the label or on the package. The regulation refers to both domestic and foreign products. More details on organic food can be found in [GAIN Report RO6023](#).

## **SECTION III. PACKAGING AND CONTAINER REQUIREMENTS**

Please see the specific section in the EU 27 FAIRS Report [E47056](#).

## **SECTION IV. FOOD ADDITIVE REGULATIONS**

Order 438/295/2002 defining and listing additives permitted for use in foodstuffs was modified through Order 154/2005 and Order 119/2007 transposing the provisions of Directive 2006/33. For further details please see the specific section in the EU 27 FAIRS Report [E47056](#).

## SECTION V. PESTICIDE AND OTHER CONTAMINANTS

Order 299/2006 issued by the Veterinary and for Food Safety Authority lays down the provisions for testing for presence of contaminants in non-animal origin products, pesticides residues, including control and surveillance on genetically modified food and feed.

### A. Pesticides and substances residues

The above-mentioned Order sets the frequency of testing for pesticide residues in non-animal origin products. The laboratories included in the National Institute for Veterinary Public Health are responsible for conducting tests for determining the presence and level of these pesticides in foodstuffs. The maximum levels of pesticides residues in and on fruits, vegetables, grains and other products of non-animal origin are provided by Order 12/2006, issued by Veterinary Authority jointly with Ministry of Agriculture and Ministry of Public Health. However, this order has been recently amended to reflect the new changes in legislation at EU level, namely [Council Directive 86/362/EEC](#) establishing MRLs for pesticides in cereals and cereal products, [Council Directive 90/642/EEC](#) establishing MRLs for pesticides in products of plant origin, including fruits and vegetables and [Commission Directive 2007/7/CE](#).

The Veterinary Order 95/2007 establishing the measures for surveillance and control of certain substances and their residues in live animals and their products, as well as residues of veterinary medicines in products of animal origin transposed the [Council Directive 96/23/CEE](#) in this field.

### B. Contaminants

The Veterinary Order 299/2006 sets the frequency of testing for contaminants, such as aflatoxin, ochratoxin A, cadmium, lead, 3-MCPD, nitrates etc. The laboratories included in the National Institute for veterinary Public Health are responsible for conducting tests for determining the presence and level of these contaminants in foodstuffs. The maximum levels are provided by the Annex of [Regulation 1831/2003](#).

## SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

### Phytosanitary regulations

Specific marketing and technical rules were approved in 2005 by the Ministry of Agriculture for cereals seeds production (Order 1262/2005), fodder plants (Order 1263/2005), vegetables propagating and planting material, other than seeds (Order 1269/2005), potato seeds (Order 1266/2005), oil and fiber plants seeds (Order 1269/2005), beet seeds (Order 1265/2005), propagating material of ornamental plants (Order 1268/2005), oilseeds (Order 1264/2005), vegetables (Order 1366/2005). All these regulations define types of seeds (basic seeds, certified seeds, commercial seeds etc.) for each of the plant varieties. Clear procedures for seed testing, labeling, marking, and packaging are provided further for each of the plant varieties and for each seed type. Import requirements for seeds originating from third countries are also provided, specifically for each seed type and its multiplication process. During 2007, all these orders have been altered in certain extent to incorporate the corresponding EU provisions. For more details please see <http://useu.usmission.gov/agri/>.

Methods of analysis and official control on fodder have been updated through Order 39/2007 by the Veterinary Authority, transposing EU legislation and cancelling the national Order 15/2004. The order sets methods of analysis for humidity, azotates, fosfor, oils and fats.

## Veterinary regulations

Romania applies the EU regulations in respect to animal products imports from third countries. As a result, Romania no longer accepts goods, such as pork meat, beef meat and poultry meat from non-EU approved establishments. Detailed information on veterinary requirements for imports of animal origin products, including a list of U.S. establishments approved for EU exports, can be viewed by accessing the website <http://useu.usmission.gov/agri/>.

The national legislation referring to Avian Influenza was repealed and replaced by Order 54 issued by the Veterinary Authority, transposing the [Council Directive 2005/94](#) on Community measures for the control of Avian Influenza. In addition, Order 37/2007 issued by the same Authority, transposed the [Commission Decision 2006/563](#) concerning certain protection measures in relation to highly pathogenic avian influenza of subtype H5N1 in wild birds in the Community.

The Veterinary Order 38/2007 transposes the [Commission Decision 2006/168](#) regarding the requirements for bovine embryos import from third countries. The Order includes the Health Certificate required by the Veterinary Authority.

In December 2006, Romanian Government approved Decision 1700 regarding the new strategic plan for Classical Swine Fever eradication. This disease is endemic in Romania and it had already triggered an EU ban on all Romanian pig and pork exports starting with 2003. The new plan includes vaccination with “live” vaccine of all backyard pigs and wild boar using baits, while commercial pig herds are vaccinated with “marker” vaccines. This vaccination was necessary after Romania registered 780 outbreaks of CSF in 2006. The vaccination will continue towards the end of 2007. More details can be found in [GAIN Report 6021](#).

## SECTION VII. OTHER SPECIFIC STANDARDS

### A. Novel foods

Please see the EU GAIN Report [E47056](#).

### B. Dietetic or special use food

Please see the EU GAIN Report [E47056](#).

### D. Food Supplements

Food Supplements are regulated by the Order 1228/244/2005 approved by Ministry of Agriculture and Ministry of Public Health. According to this regulation, food supplements can be presented on the market in any of the form of tablets covered or uncovered, capsules, jellies, pastes, candies or bars, juices, liquids, powders, or other liquid forms, ampoules of liquids, drop dispensing bottles, which contain nutritional substances for human diet. The Order remains valid.

### E. Organic Food

The Ministry of Agriculture approved Order 219/2007 providing instructions for producers, processors, and importers of organic products. According to this Order, published in addition to Emergency Ordinance 34/2000 on organic products, all operators in this field have to register with the Ministry of Agriculture, through its specialized department. The operators

have to fill-out certain forms and submit them to Min. of Agriculture before June 1 every year. No inspection and certification will be granted to un-registered operators.

## **F. Products derived from Biotechnology**

The regulatory framework to ensure full traceability of biotech products in Romania is the GOR Decision 173/2006 transposing [Regulation \(EC\) No 1830/2003](#). According to this Decision, all operators involved in this business along the commercial chain must transmit and retain information about products that contain or are produced from GMOs at each stage of placing them on the market. Accurate information concerning the presence of GMOs must be must be retained for five years. The regulation covers all products, including food and feed, containing or derived from GMOs that received a national authorization.

Traceability elements are also provided in the Order 237 issued by MARD in 2006, amended by Order 471/2007. According to this order, biotech farmers have to seek for authorization from the county office of MARD, for each plot intended to be cultivated with GM crops. The issuance of such an authorization is subject to all other regulations in place.

When delivering the GM products further on the commercial chain, farmers have to clearly specify on the accompanying documents and labels the GM product unique identifier and the fact that the products are genetically modified.

For further details on biotechnology regulations you can read the [GAIN Report 7003](#).

## **SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS**

Intellectual property laws are in place in Romania. Each company is responsible for protecting its intellectual property rights. Although enforcement has been improving lately, the authorities still struggle to become more effective. Romania is signatory to a number of international Intellectual Property Rights conventions.

### **Invention patents and Trademarks**

The Romanian Law protects the invention acts through patents. The applications, including a description of the invention, must be submitted in the Romanian language to the State Office for Inventions and Trademarks (OSIM). When written in another language, a translation into Romanian of the already submitted documentation must be provided within two months. Law 64 of October 1991 with subsequent updates and rules of application regulates the invention patents.

Specific rules on Trademarks registration in the National Trademarks Registry, applications submittal, renewal, trademarks publication, property rights change of ownership, international trademarks registration are provided by Law 84/1998 and its application rules.

### **Copyrights**

The Romanian Office for Copyrights handles the issues related to copyrights. The main piece of legislation governing Copyrights is Law 8/1996 with subsequent amendments. Foreigners, will be treated according to the international agreements signed by Romania, while in the absence of such agreements, the foreigners will be treated equally as Romanian citizens, assuming the same treatment is endorsed in their country for the Romanian citizens.



U.S. companies might find that copyright enforcement is still inadequate in Romania. The Romanian Office for Copyrights, the State Office for Inventions and Patents and the General Customs Department collaborate to solve copyright infringements.

## **SECTION IX. IMPORT PROCEDURES**

### **Non-animal origin products**

The import and export conditions for products of non-animal origin are regulated in Order 159/2006. The importer has to provide the border entry point through the goods will pass detailed information about the shipment with 24 hours before arrival. Each shipment has to be accompanied by this notification in original. Placing on the market of the imported goods will be allowed upon presenting the authorities with the test results for contaminants, pesticide residues etc.

### **Animal origin products**

The conditions and the sanitary veterinary procedure for import, export, and transit of live animals, products and by-products of animal origin, fodder and products of veterinary use are stated by Order 138/2005 issued by the VFSNA, subsequently amended through Order 13/2006. Its provisions were presented in the [GAIN Report 6001](#) and [GAIN Report 6016](#).

For further details on health certificates and import requirements you can read [E47056](#).

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**The Ministry of Public Health**

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Bucharest, Romania  
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**The National Sanitary-Veterinary and for Food Safety Authority**

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**The Ministry of Environment and Sustainable Development**

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